

Table 1. Continued	
Variable	Mean (SD)
Age (years)	34.5 (10.5)
Gender	
Male	50.0%
Female	50.0%
Marital status	
Married	60.0%
Single	40.0%
Education (years)	12.5 (2.5)
Occupation	
Professional	30.0%
Managerial	20.0%
Clerical	10.0%
Service	20.0%
Unemployed	20.0%
Income (USD/month)	1,200 (500)
Health status	
Good	70.0%
Fair	20.0%
Poor	10.0%
Smoking status	
Smoker	30.0%
Nonsmoker	70.0%
Alcohol consumption	
Regular	10.0%
Occasional	20.0%
Never	70.0%
Exercise frequency	
Regular	20.0%
Occasional	30.0%
Never	50.0%
Stress level	
High	40.0%
Medium	30.0%
Low	30.0%
Life satisfaction	
Satisfied	60.0%
Dissatisfied	40.0%
Overall health score	75.0 (15.0)

Figure 1

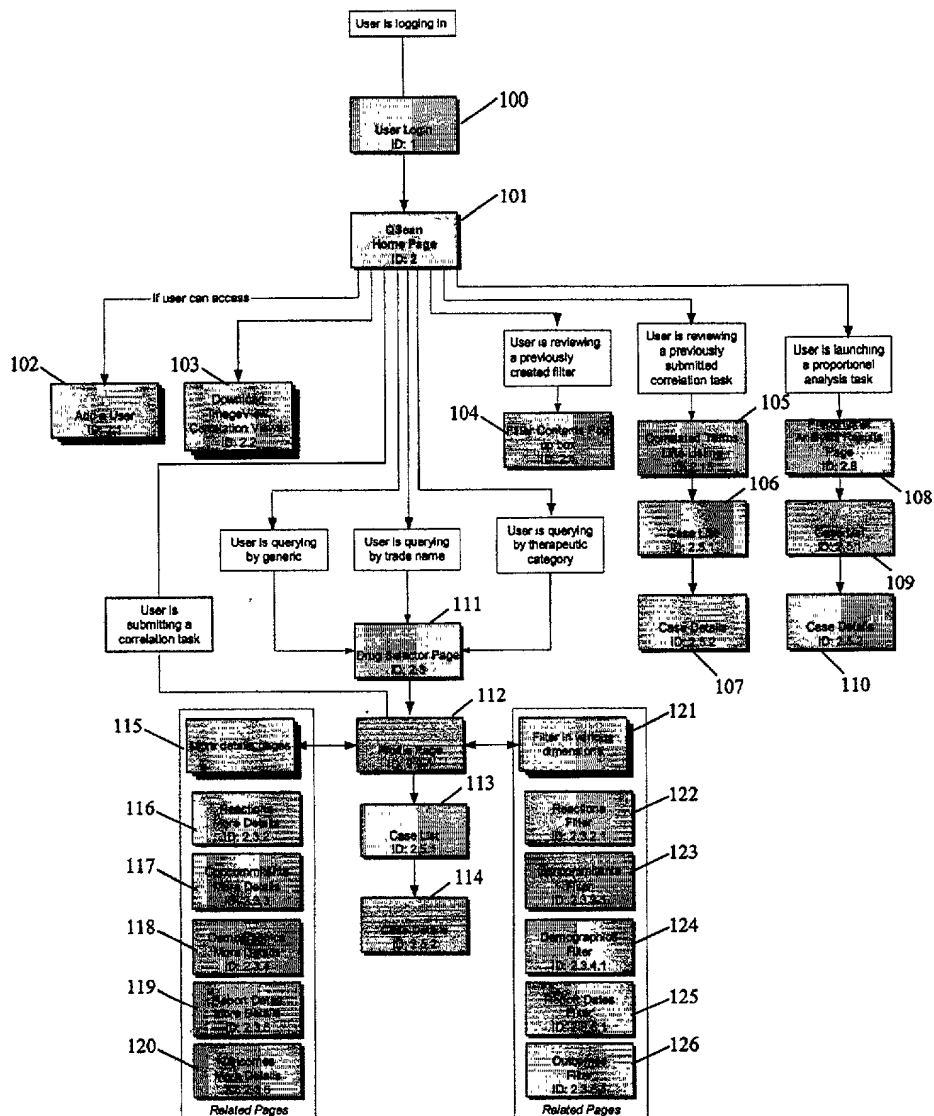
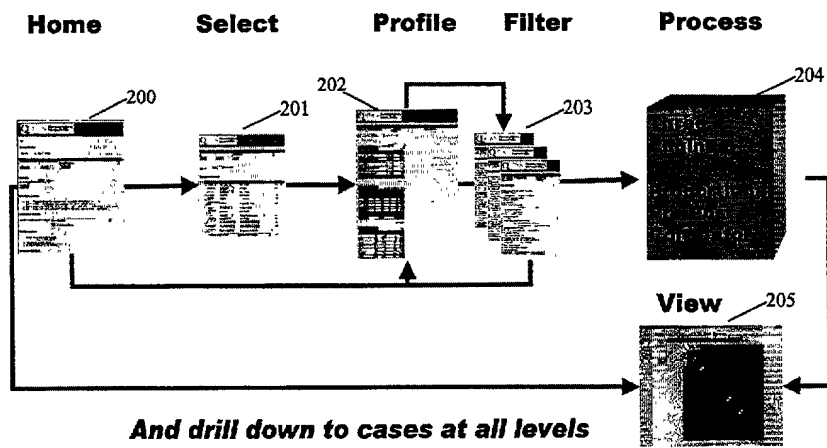


Figure 2



102030 " 30203030

Figure 3

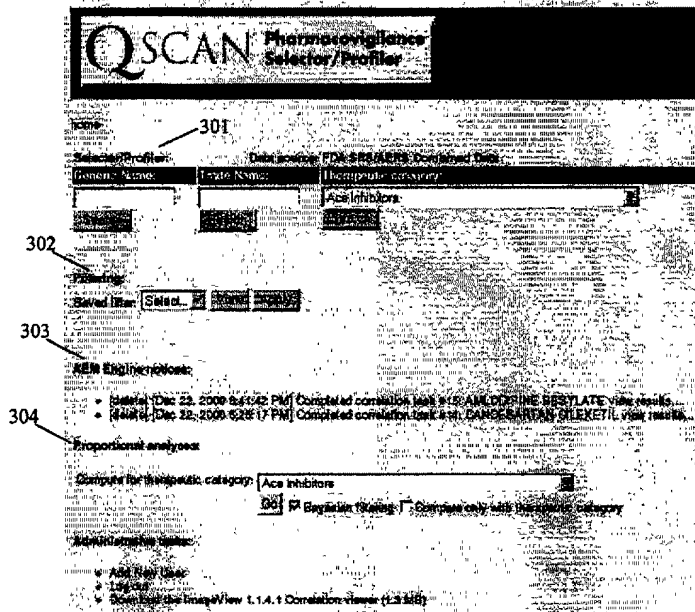
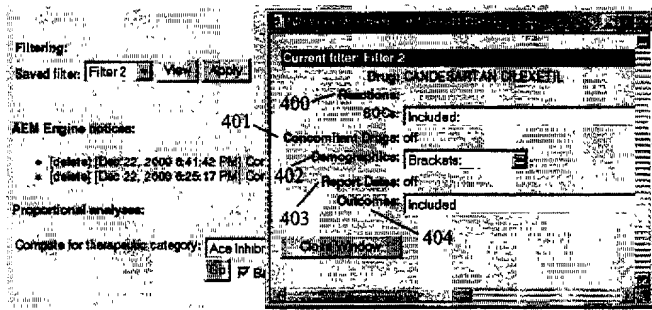


Figure 4



FOUO 92572360

Figure 5

home > drug selector

500

501

502

Selected/Profile: Data source: FDA-SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

Search Search Search

Filtering:

Saved filter: Select: [X] [X] [X]

22 drugs in category: ACE INHIBITORS

Generic Name	Trade Names	Therapeutic Categories	Refined
AMLODIPINE HYDROCHLORIDE	AMLODIPINE	Ace Inhibitors	
AMLODIPINE BESYLATE	AMIODIPINE	Ace Inhibitors	
BENAZEPRIL HYDROCHLORIDE	BENAZEPRIL	Ace Inhibitors	
CANDESARTAN CILEXETIL	ATACAND	Ace Inhibitors	
CAPTROPIL	ACE-HEMMER	Ace Inhibitors	
ENALAPRIL MALEATE	ACETENSIL	Ace Inhibitors	

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Figure 6

600	Data Pedigree	601	602	603	604	605	606	607
Map To	Verbatim	Source	Incidents	Case Count	CDRx Processing	Cross-reference	First/Last Reported Reactions	
PROZAC	PROZAC	SRS	47953	47937		Orange Book	Apr 27 1969/Dec 2 1997	
PROZAC	Prozac	AERS	3378	3308	S	Orange Book	Nov 1 1997/Jun 29 1999	
FLUOXETINE	FLUOXETINE HYDROCHLORIDE	SRS	2204	2203		NDCD Tradename	Jan 1 1979/Oct 14 1997	
FLUOXETINE	Fluoxetine	AERS	574	571	S	NDCD Tradename	Nov 1 1997/Jun 18 1999	
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	379	378		M Orange Book	Nov 1 1997/Jun 12 1999	
PROZAC	Prozac (Fluoxetine)	AERS	140	140		M Orange Book	Nov 7 1997/Apr 24 1999	
FLUOXETINE	Fluoxetine Hydrochloride	AERS	122	122	S	Orange Book	Nov 14 1997/Jun 27 1999	
FLUOXETINE	Fluoxetine (Fluoxetine Hydrochloride)	AERS	85	85		M Orange Book	Mar 1 1998/Jun 24 1999	
FLUOXETINE	Fluoxetine Hcl	AERS	34	34		Orange Book	Nov 1 1997/Nov 1 1998	
PROZAC	Prozac (Fluoxetine Hcl)	AERS	20	20		M Orange Book	Nov 1 1997/Mar 12 1999	
PROZAC	Prozac (Fluoxetine Hydrochloride)	AERS	17	17		M Orange Book		
FLUOXETINE	Fluoxetine (Fluoxetine)	AERS	15	15		M Orange Book	Nov 15 1997/Jun 6 1999	

Downloaded from www.ascp.com

Figure 7

700

701

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704

703

more details.

Reactions		
View: HLT (256 of 1495) filter		
Top 10 HLTs of 256	Reaction Count	% of Reactions
Hypertension and increased blood pressure NEC	68	3.88%
General symptoms and signs NEC	57	3.25%
Disturbances in consciousness	52	2.97%
Renal function analyses	46	2.63%
Headaches NEC	46	2.63%
Cardiac function diagnostic procedures	46	2.63%
Neurological signs and symptoms NEC	45	2.57%
Nausea and vomiting (all forms)	43	2.45%
Asthenic conditions	43	2.45%
Vascular tests NEC including blood pressure	42	2.40%
Top 10 HLTs	488	Total reactions 1752

102050" 01012050

Figure 8

Concomitant Drugs

801 802 filter.

	Suspect		Non-suspect			
Top 10 drugs	S	NS	S	NS	Total	%
HYDROCHLOROTHIAZIDE	9	36	0	0	45	10.79%
ASPIRIN	2	38	0	5	45	10.79%
FUROSEMIDE	2	32	0	1	35	8.39%
DIGOXIN	0	30	0	0	30	7.19%
AMLODIPINE BESYLATE	0	24	4	0	28	6.71%
ENALAPRIL MALEATE	4	15	0	5	24	5.76%
VERAPAMIL HYDROCHLORIDE	11	10	0	2	23	5.52%
ESTROGENS, CONJUGATED	0	23	0	0	23	5.52%
METOPROLOL SUCCINATE	8	11	0	3	22	5.28%
METOPROLOL TARTRATE	0	15	0	7	22	5.28%
Non-suspect						
	Suspect		Non-suspect			
Total	Total		Total		Total	
	172		1141		1313	

more details.

102020" 323T2500

Figure 9

900

Demographics

901

filter

Age Group	Male	Female	Unknown	Total	%
>75	18	73	0	91	21.82%
51-75	89	123	1	213	51.08%
31-50	30	16	0	46	11.03%
16-30	2	1	0	3	0.72%
<16	0	0	0	0	0.00%
Unknown	11	30	23	64	15.35%
Total	150	243	24	417	
%	35.97%	58.27%	5.76%		

more details

FOIA b 7 - D

Figure 10

1000 1001 1002

Report Dates

filter

Timeframe	Count	%
1990-1999	446	100.00%
Total Report Dates		
	446	

more details...

Report Dates

Figure 11

1100 1101 filter... 1102

Outcomes		
Outcome	Count	%
DEATH	36	7.19%
DISABILITY	16	3.59%
HOSPITALIZATION - INITIAL OR PROLONGED	231	46.11%
LIFE-THREATENING	46	9.18%
OTHER	168	33.53%
REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE	2	0.40%
Total serious outcomes	333	
Total non-serious outcomes	168	
Total outcomes	501	

more details...

FOIA b 7 - D

Figure 12

☒ Reactions |
 ☐ Drugs |
 ☐ Outcomes |
 ☐ Report Sources |
 ☐ Timeframes |
 ☐ Demographics |
 ☐ Cases |
 ☐ Filter Notes

deafness

☒ Reactions
☒ blood and lymphatic system disorders
☒ cardiac disorders
☒ congenital and familial genetic disorders
☒ ear and labyrinth disorders
☒ external ear disorders (exc congenital)
☒ hearing disorders
☒ deafness and hyperacusis
☒ deafness conductive (exc otosclerosis)
☒ deafness neurosensory
☒ deafness permanent
☒ deafness transitory
☒ dysacusis
☒ hearing impaired
☒ hearing impairment acute
☒ hyperacusis
☒ hypoacusis
☒ presbycusis
☒ inner ear and with cranial nerve disorders
☒ middle ear disorders (exc congenital)
☒ miscellaneous ear disorders
☒ endocrine disorders
☒ eye disorders
☒ gastrointestinal disorders

Generate profile for this filter (This Filter has not been profiled)

[illegible]1303

Figure 14

Correlation Details
Analyzed Drug: CANDESARTAN CILEXETIL
Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

1401 Cases 1 to 18 of 18 cases 1402 1403 1404 1405 1406 1407 1408

Case ID	Sex	Manufacturer Control Code	FDA Report Receipt Date	Age	Drugs	Reactions	Serious
1 3263641	F	19990300088	1999-06-17	74	Atacand	Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated	N
2 3198047	F	19990200143	1999-03-12	57	Acuretic, Atonvastatin, Atacand, Cefixime, Nitro-Dur, Terbesmin Expectorante	Blood Creatinine increased, blood urea increased; Hypotension NOS; Renal Failure Acute	Y
3 3171644	F	19981100002	1999-01-17	69	Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Clantol, Antivert, Pyndium, Zolof, Dyazide, Verapamil - Slow Release, Ambien	Abdominal Pain Nos, Blood Creatinine Increased; Blood Urea Increased, Coronary Artery Disease Nos, Haemoptysis, Heart Rate Increased, Hypertension Aggravated; Renal Failure Acute	N
4 3270258	F	19990400489	1999-06-26	75	Atacand, Hydrochlorothiazide	Arrhythmia; Block Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram ST Segment Depression, Electrocardiogram U Wave Appearance; Electrolyte Imbalance; Hyponatraemia; Hypokalaemia; Hypotension; Loss Of Consciousness Nec; Renal Impairment Nos; Syncope	N

Figure 15

Correlation Details																																								
Analyzed Drug: CANDESARTAN CILEXETIL																																								
Case for Term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]																																								
1501	Case ID:	3198047																																						
1502	Sex:																																							
1503	Age:	57.0 years, 0.0 months																																						
1504	Reactions:	<table><thead><tr><th>As Reported</th><th>Preferred Term</th><th>High Level Term</th><th>High Level Group Term</th><th>System Organ Class</th></tr></thead><tbody><tr><td>Blood Creatinine Increased</td><td>Blood Creatinine Increased</td><td>Renal function analyses</td><td>Renal and urinary tract investigations and urinalysis</td><td>Investigations</td></tr><tr><td>Blood Urea Increased</td><td>Blood Urea Increased</td><td>Renal function analyses</td><td>Renal and urinary tract investigations and urinalysis</td><td>Investigations</td></tr><tr><td>Hypotension NOS</td><td>Hypotension NOS</td><td>Hypotension</td><td>Decreased and non-specific blood pressure disorders and shock</td><td>Vascular disorders</td></tr><tr><td>Renal Failure Acute</td><td>Renal Failure Acute</td><td>Renal failure and impairment</td><td>Renal disorders (exc. nephroses)</td><td>Renal and urinary disorders</td></tr></tbody></table>				As Reported	Preferred Term	High Level Term	High Level Group Term	System Organ Class	Blood Creatinine Increased	Blood Creatinine Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations	Blood Urea Increased	Blood Urea Increased	Renal function analyses	Renal and urinary tract investigations and urinalysis	Investigations	Hypotension NOS	Hypotension NOS	Hypotension	Decreased and non-specific blood pressure disorders and shock	Vascular disorders	Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (exc. nephroses)	Renal and urinary disorders										
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Renal Failure Acute	Renal Failure Acute	Renal failure and impairment	Renal disorders (exc. nephroses)	Renal and urinary disorders																																				
1505	Concomitant Drugs:	<table><thead><tr><th>Name</th><th>Dose</th><th>Route</th><th>Suspect</th><th>Status</th></tr></thead><tbody><tr><td>Acuretic</td><td>TAB QD</td><td></td><td>Yes</td><td></td></tr><tr><td>Atorvastatin</td><td></td><td></td><td>No</td><td></td></tr><tr><td>Alacand</td><td>16 MG QD PO ORAL</td><td></td><td>Yes</td><td></td></tr><tr><td>Cefixime</td><td></td><td></td><td>No</td><td></td></tr><tr><td>Nitro-Dur</td><td></td><td></td><td>No</td><td></td></tr><tr><td>Terbutalin Expectorante</td><td></td><td></td><td>No</td><td></td></tr></tbody></table>				Name	Dose	Route	Suspect	Status	Acuretic	TAB QD		Yes		Atorvastatin			No		Alacand	16 MG QD PO ORAL		Yes		Cefixime			No		Nitro-Dur			No		Terbutalin Expectorante			No	
Name	Dose	Route	Suspect	Status																																				
Acuretic	TAB QD		Yes																																					
Atorvastatin			No																																					
Alacand	16 MG QD PO ORAL		Yes																																					
Cefixime			No																																					
Nitro-Dur			No																																					
Terbutalin Expectorante			No																																					
1506	Outcomes:	HOSPITALIZATION - INITIAL OR PROLONGED (HO) LIFE-THREATENING(LT)																																						
1507	Manufacturer Control Code:	0990200143																																						
1508	Manufacturer Date:	1999-03-5																																						
1509	Adverse Event Date:	1998-12-13																																						
1510	Report Type:	EXP																																						
1511	Report Source:	OTH																																						
1512	Case Source:	AERS																																						
1513	Narrative:																																							

FOI20250312000

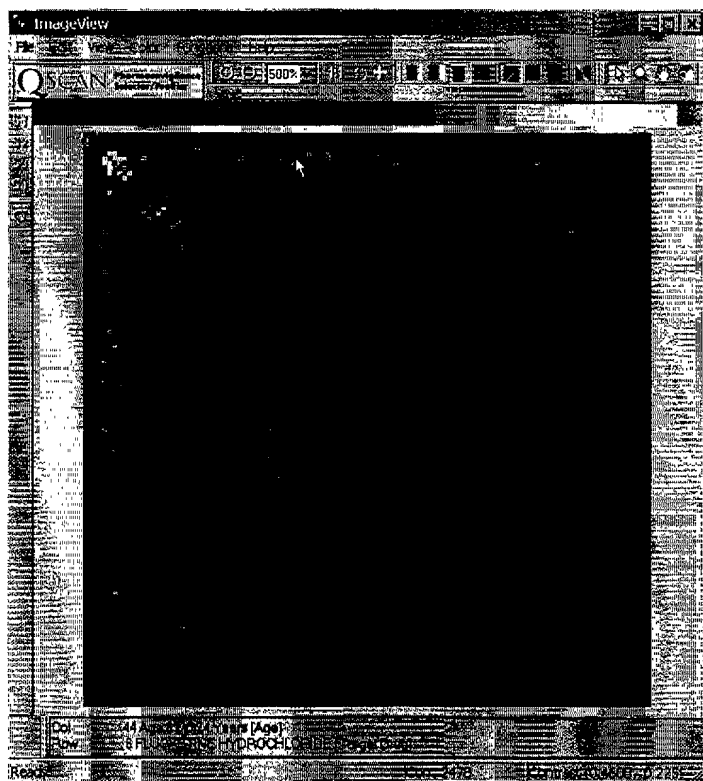
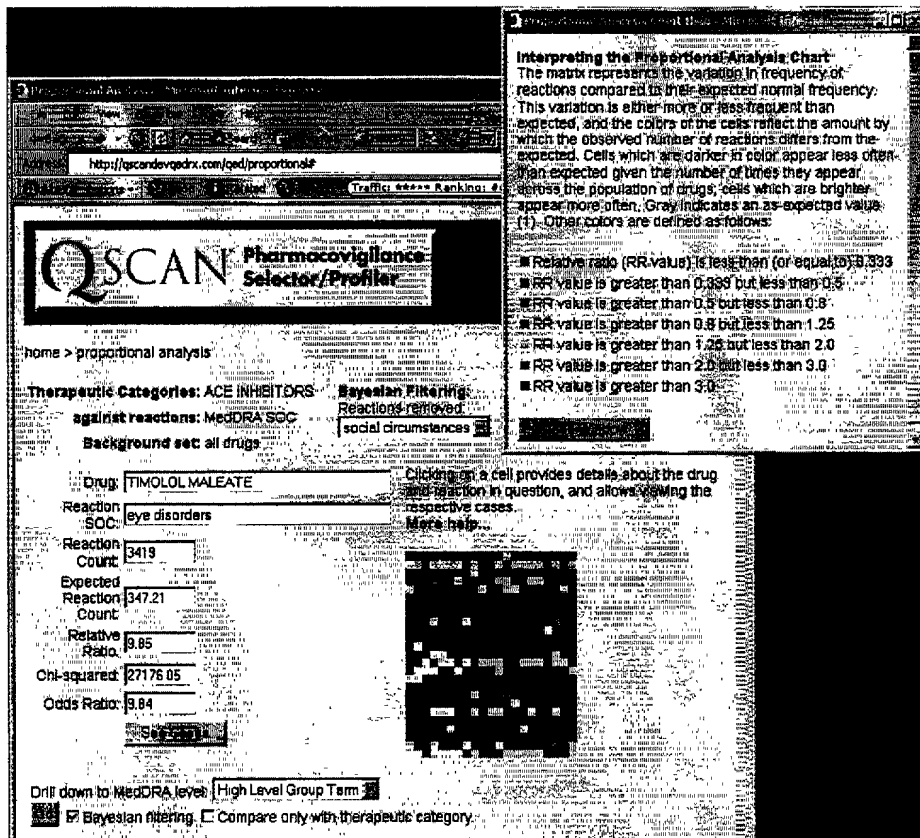
[illegible]

Figure 17



FOUO "SECRET"

Figure 18

Proportional Analysis	
[ACE-INHIBITORS] vs. Reactions (SOCs)	
View by HICs	
1800	Drug: AMLODIPINE BESYLATE
1801	Reaction: Surgical and medical procedures
1802	Reaction Count: 927
1803	Expected Reaction Count: 201.02
1804	Relative Ratio: 4.61

20250925T1800

Figure 19

550 entries for this analysis are displayed below.

Correlated Terms		1900	1901	1902	1903	1904
[Reaction]	[Drug]			[Count]	[Expected Count]	[Relative Ratio]
1 6: Eye disorders	19: TIMOLOL MALEATE			3392	346.3	9.8
2 24: Surgical and medical procedures	2: AMLODIPINE BESYLATE			1732	200.4	8.6
3 14: Metabolism and nutrition disorders	1: AMILORIDE HYDROCHLORIDE			838	266.5	3.1
4 24: Surgical and medical procedures	13: METHYLDOPA			37	15.6	2.4
5 16: Neoplasms benign and malignant (including cysts and polyps)	17: RESERPINE			65	28.6	2.3
6 4: Ear and labyrinth disorders	4: CANDESARTAN CILEXETIL			32	14.3	2.2
7 24: Surgical and medical procedures	20: TRANDOLAPRIL			13	6	2.2
8 14: Metabolism and nutrition disorders	18: SPIRONOLACTONE			1330	516.1	2.2

FOI b7 - D

Variable	Mean	SD	Min	Max
Age	34.5	10.2	21	55
Gender	Male	Female		
Marital Status	Married	Single		
Education	High School	College		
Occupation	Manager	Worker		
Income	\$10,000	\$20,000		
Health Status	Good	Fair		
Exercise Frequency	Weekly	Monthly		
Stress Level	Low	High		
Sleep Quality	Good	Poor		
Dietary Habits	Healthy	Unhealthy		
Alcohol Consumption	None	Occasional		
Tobacco Use	Non-smoker	Smoker		
Family Size	2	3		
Work Hours	40	50		
Commuting Time	30	45		
Home Ownership	Owner	Renter		
Neighborhood Safety	Safe	Unsafe		
Access to Healthcare	Yes	No		
Health Insurance	Yes	No		
Chronic Conditions	None	1 or more		
Medication Use	None	Regular		
Healthcare Visits	Annual	Biannual		
Healthcare Costs	\$500	\$1,000		
Healthcare Satisfaction	High	Low		
Healthcare Access	Easy	Difficult		
Healthcare Quality	Good	Poor		
Healthcare Availability	Yes	No		
Healthcare Affordability	Yes	No		
Healthcare Accessibility	Yes	No		
Healthcare Effectiveness	Yes	No		
Healthcare Reliability	Yes	No		
Healthcare Responsiveness	Yes	No		
Healthcare Communication	Yes	No		
Healthcare Education	Yes	No		
Healthcare Empowerment	Yes	No		
Healthcare Participation	Yes	No		
Healthcare Involvement	Yes	No		
Healthcare Engagement	Yes	No		
Healthcare Collaboration	Yes	No		
Healthcare Partnership	Yes	No		
Healthcare Alliance	Yes	No		
Healthcare Coalition	Yes	No		
Healthcare Network	Yes	No		
Healthcare Community	Yes	No		
Healthcare System	Yes	No		
Healthcare Organization	Yes	No		
Healthcare Structure	Yes	No		
Healthcare Process	Yes	No		
Healthcare Outcome	Yes	No		
Healthcare Impact	Yes	No		
Healthcare Effect	Yes	No		
Healthcare Result	Yes	No		
Healthcare Benefit	Yes	No		
Healthcare Advantage	Yes	No		
Healthcare Gain	Yes	No		
Healthcare Profit	Yes	No		
Healthcare Loss	Yes	No		
Healthcare Cost	Yes	No		
Healthcare Expense	Yes	No		
Healthcare Price	Yes	No		
Healthcare Value	Yes	No		
Healthcare Quality	Yes	No		
Healthcare Safety	Yes	No		
Healthcare Security	Yes	No		
Healthcare Privacy	Yes	No		
Healthcare Confidentiality	Yes	No		
Healthcare Integrity	Yes	No		
Healthcare Honesty	Yes	No		
Healthcare Transparency	Yes	No		
Healthcare Accountability	Yes	No		
Healthcare Responsibility	Yes	No		
Healthcare Obligation	Yes	No		
Healthcare Commitment	Yes	No		
Healthcare Dedication	Yes	No		
Healthcare Devotion	Yes	No		
Healthcare Loyalty	Yes	No		
Healthcare Fidelity	Yes	No		
Healthcare Faithfulness	Yes	No		
Healthcare Trustworthiness	Yes	No		
Healthcare Reliability	Yes	No		
Healthcare Dependability	Yes	No		
Healthcare Predictability	Yes	No		
Healthcare Consistency	Yes	No		
Healthcare Uniformity	Yes	No		
Healthcare Regularity	Yes	No		
Healthcare Frequency	Yes	No		
Healthcare Periodicity	Yes	No		
Healthcare Continuity	Yes	No		
Healthcare Coherence	Yes	No		
Healthcare Consensus	Yes	No		
Healthcare Agreement	Yes	No		
Healthcare Accord	Yes	No		
Healthcare Understanding	Yes	No		
Healthcare Comprehension	Yes	No		
Healthcare Knowledge	Yes	No		
Healthcare Awareness	Yes	No		
Healthcare Insight	Yes	No		
Healthcare Understanding	Yes	No		
Healthcare Perception	Yes	No		
Healthcare Sensation	Yes	No		
Healthcare Feeling				

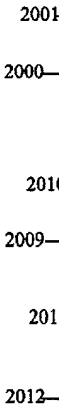


Figure 21

home > drug select > drug profile > case list

Diag: BENAZEPRIL HYDROCHLORIDE

Reactions: SOCs: Includes

Concomitant Drugs:

Descriptive: of

Report Dates: of

Date: of

Summary view: Cases 1 to 50 of 269 cases

6 pages: 1 51 101 151 201 251 2101 2102 2103 2104 2105 2106 2107

Case ID	Sex	Manufacturer	Central Code	Report Date	Age	Drugs	Reactions	Seizures
1	3510123	F	20001017488E	2003-05-1		Tylenol, Advil, Duragesic, Aspirin, Acetaminophen Ex-Est, Advil, Lotensin, Zyrtec, Celebrex, Benadryl, Premarin, Lasix, Hctz 25 Mg, Hydrocodone, Immune Globulin Intravenous (Human), Gammanon N 10% - Placebo, Inderal, Xylocaine, Claritin, Glucophage, Methylprednisolone, Nasonex, Singulair, Proloset, Oxygen, Pazol, SoluMedrol Pack, Rezulin 200 Mg Am	Cardiac Monitor Nos, Dyspepsia, Dyspnea Nos, Oedema Lower Limb, Pain In Limb, Phlebitis Nos, Physical Examination Nos Abnormal, Rhinorrhea, Tenderness Nos, Venous Thrombosis Deep Limb	Y
2	CD1579035	F	97USA0061	1997-08-1		LOTENSIN	Hypotension NOS, Tablet in stool	N
3	3204366	F	96061673	1993-08-26		Aspirin Coated, Lotensin, Naproxen	Asthma, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain Nos	Y
4	CD1456473	F	93364001	1994-05-26		LOTENSIN	Nausea, Vasodilation	N

202050 99513660